COALITION FOR GOVERNMENT PROCUREMENT
RESPONSES TO QUESTIONS ASKED AT MARCH 4 MEETING WITH OMB

Doesn't Sec. 703 of the NDAA for FY 2008 Refer to All Prescriptions of Covered Drugs?

Section 703 literally requires DoD to pay no more than the procurement ceiling prices in 38 U.S.C. 8126 for prescriptions purchased from retail pharmacies. The proposed rule is a practical means to achieve the spirit of section 703, but the language of the statute cannot be implemented literally through a rebate agreement. Because DoD pays retail pharmacies a prescription price that exceeds the bulk wholesale price paid to manufacturers, when DoD offsets a manufacturer rebate against the prescription price, the amount paid exceeds the discounted wholesale price in section 8126. Likewise, a program intended to leverage a desire for formulary status through voluntary rebate agreements cannot literally apply to every prescription paid by the Tricare retail pharmacy program, because some prescriptions are dispensed by providers that purchased the drugs at deeply discounted prices under a different federal program, some drugs covered by section 8126 are generics, some drugs are already excluded from the formulary, and some manufacturers may not participate in the program. The statute, however, grants DoD flexibility in implementing the statute by imposing the requirement "to the extent practical."

Is the Proposed Tricare Rebate Program like the Medicaid Drug Rebate Program?

Like the Medicaid drug rebate program, the proposed Tricare retail pharmacy drug rebate program depends on manufacturer willingness to provide rebates on prescriptions purchased from retail pharmacies in accordance with prescribed terms. However, the Medicaid rebate statute guarantees formulary status of covered drugs in exchange for an agreement to pay specified rebates on those drugs, regardless of how the drugs compare to others in the same therapeutic class. By contrast, the Tricare proposed rule does not guarantee formulary status because DoD conducts class reviews and excludes those drugs it determines are not clinically effective and cost effective from the formulary. Under the existing regulation, drugs that are removed from the formulary are designated non-formulary. Accordingly, the Tricare proposed rule seeks to induce manufacturers to agree to pay specified rebates on drugs granted formulary status by making such an agreement a condition of formulary status. Requiring rebates on drugs designated non-formulary would be a powerful disincentive to participation in the program.

What is the Impact of Retroactive Agreements on Pharmaceutical Manufacturers?

Not all pharmaceutical companies are large. There are many small pharmaceutical companies with few covered drugs that are struggling to make a profit. The Proposed Rule did not assess the impact on small businesses of a requirement to make a large initial payment to DoD covering past transactions in addition to rebates on new sales, as is required by law. Conditioning future Tricare formulary status on a new agreement to pay DoD 24% of the proceeds received from wholesaler sales over the past year will reduce current year revenue and cause economic injury. Even for some large manufacturers facing significant challenges in the current economic environment, having to pay a large sum to DoD as the price to get on formulary could have a detrimental impact on their financial health. Manufacturers who cannot afford to pay rebates on past prescriptions in an effort to secure future business will be unfairly disadvantaged.